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(54) Diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause

(57) The present invention relates to a diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, characterized in that the assembly comprises, on a supporting strip, a first region, where is located an anti-FSH monoclonal antibody, a second region adjoining the first region, where is located a polyclonal antibody, and a third region, adjoining the second region, where is located a FSH-antibody which can bind with the monoclonal antibody, an imbibition layer having at least a portion thereof superimposed on the first region being moreover provided.

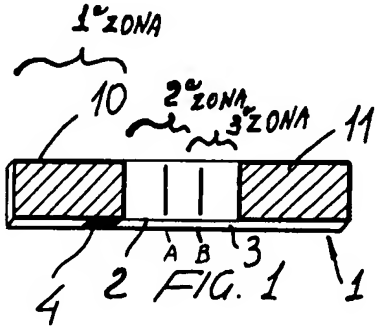

FIG. 1

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Description

BACKGROUND OF THE INVENTION

The present invention relates to a diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause.

As is known, the term "menopause" usually indicates the stop of the menstruation, with which a lacking of fertility is associated, since the ovary function has been exhausted and no further ovulation occurs and in which, sometimes, occur a series of signs and symptoms which can negatively effect the woman.

Usually the menopause is preceded by a period having a duration which can vary from some months to two or three years, in which great menstrual unevennesses can be present.

In the pre-menopause period, the ovary activity, i.e. the ovulation, as well as the production of estrogens and progesterone and the like, will decrease and progressively exhaust.

Such a decrease and exhaustion of the ovary activity must be timely diagnosed.

The progressive reduction of the estrogen production is also associated with an alteration of the lipide and bone metabolism which cause woman to be easily subjected to osteoporosis and cardiovascular pathologies. Medical treatments, on the other hand, can prevent these pathologies from occurring, but they must be timely started upon a diagnosis of menopause and exhaustion of the ovary function.

The diagnosis of menopause is based on an evidence of a stop of the menstruation, because of an exhaustion of the ovary activity.

Such a diagnosis is based on an appearance of signs and symptoms, such as vasomotor symptoms, i.e. bursts of heat occurring in a very large number of women, neurovegetative symptoms, such as tachycardia, paresthesia, dizziness, insomnia and the like, as well as psychosomatic symptoms, such as fatiguing, irritability, anxiety and the like, in addition to local genital symptoms such as vaginal dryness, dispareunia and the like.

The most evident endocrine modification consists of a persistent increase of the follicle stimulating hormone, also known as "FSH".

Contemporaneously the estrogens decrease and the LH, that is the luteinizing hormone increases.

Generally, the main diagnostic marker is the FSH, which has a comparatively high value even in menopause and, accordingly, allows to timely detect a reduction and exhaustion of the ovaric function.

At present, in order to properly detect the FSH, the latter is metered into the blood by immunoenzimatic methods or radioimmunologic methods on serum, by using specifically designed instruments. The metering, which can be carried out exclusively by specialized medical personnel, involves a blood take-up operation and a hormone determination at an analysis laboratory.

Such a method involves a comparatively high cost and, mainly, a great discomfort for the patient.

SUMMARY OF THE INVENTION

Accordingly, the aim of the present invention is to overcome the above mentioned problem, by providing a diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, which allows the menopause test to be performed at home without requiring invasive blood collecting methods and affording the possibility of frequently repeating the test without any discomfort for the patient.

Within the scope of the above mentioned aim, a main object of the present invention is to provide such a diagnostic test assembly which provides a very accurate response in a time period of the order of few minutes, with a result truly indicative of a menopause condition.

Another object of the present invention is to provide such a diagnostic test assembly which is very reliable and safe in operation.

Yet another object of the present invention is to provide such a diagnostic test assembly which is very competitive from a mere economic standpoint.

According to one aspect of the present invention, the above mentioned aim and objects, as well as yet other objects, which will become more apparent hereinafter, are achieved by a diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, characterized in that said assembly comprises, on a supporting strip, a first region where is located an anti-FSH monoclonal antibody (4), a second region, adjoining the first region, where is located a polyclonal anti-FSH antibody (2), and a third region, adjoining the second region, where is located an anti-immunoglobuline IGG antibody (3) which can bind with said monoclonal anti-FSH antibody.

BRIEF DESCRIPTION OF THE DRAWINGS

Further characteristics and advantages will become more apparent hereinafter from the following detailed disclosure of a preferred, though not exclusive, embodiment of a diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, which is illustrated, by way of an indicative, but not limitative, example, in the figures of the accompanying drawings, where:

Figure 1 is a schematic view illustrating a strip thereon are arranged the chemical reagents;
Figure 2 illustrates the strip arranged in an user envelope;
Figure 3 is a schematic view illustrating the starting step of a test providing a positive result;
Figure 4 illustrates the end step of a test providing a positive result;

Figure 5 illustrates the starting step of a test providing a negative result;

Figure 6 illustrates the end step of a test providing a negative result;

and

Figure 7 schematically illustrates the evolvement of the FSH hormone in the menstrual cycle.

DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to the number references of the above mentioned figures, the diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, according to the present invention, comprises a supporting strip 1, on which is provided a first region 2, where has been deposited and adhered in a dry form an anti-FSH polyclonal antibody, obtained from the rat, and which is commercially available.

The deposition can be performed either manually or automatically and is usually carried out at about 2.5 cm from the left end portion of the strip.

The anti-FSH antibody, which is colourless, is allowed to dry at room temperature and has an use concentration corresponding to the detection and responsibility requirements of the test.

The selection of the specific anti-FSH polyclonal antibody derives from the fact that it is necessary to perform a natural immunological reaction, under controlled conditions, between said antibody and the FSH antigen, that is the follicle stimulating hormone, which must be detected and which is considered to be present in a menopause woman urine at a detectable concentration, indicative of the menopause condition.

By the same deposition method, a second region 3 is made adjoining the first region 2, which second region 3 is arranged at about 3.5 cm from the left end portion of the strip, by causing an anti-immunoglobuline anti-antibody, in dry form, to adhere to the strip, which is also of a commercially available type.

Adjoining the region 2, at the portion thereof opposite to the region 3, there is formed a first region 4, having an anti-FSH monoclonal antibody, which is obtained by means of an immunization of a cavy animal, and also of a commercially available type.

On the left end portion of the supporting strip 1 there is moreover applied an imbibition layer 10, which is advantageously constituted by an absorption paper, bound on the cellulose acetate strip by means of natural organic glues; moreover, the application or imbibition layer 10 is superimposed on the first region, where is provided the anti-FSH monoclonal antibody.

The anti-FSH monoclonal antibody, in particular, is chemically bound by affinity with colloidal gold, for the intended specific applications, and is adapted to bind with the anti-immunoglobuline anti-antibody, as it will become more apparent hereinafter.

Finally, an absorption layer 11 is provided on the right end portion of the supporting strip 1, which layer 11 does not have any operating activity, but provides, in actual practice a stop layer against the absorption of the reaction liquid excess.

Advantageously, the thus prepared strip 1 is packaged within an envelope 20, having a circular hole 21 superimposed on the imbibition layer 10 and a double window 22, arranged at the second and third regions, and being provided, at the two regions, with indicating elements S and C which respectively correspond to a positive response and to a control.

By the above disclosed test assembly it is possible, starting from a woman urine, to deposit 5-7 drops at the window 21, so as to detect a possible presence of the hormone in the examined sample, at a concentration equal to or greater than 20 ml.U./ml.

The reaction, migration and colour fixation time, being indicative of the response, will be of about 8 minutes.

The urine will wet the layer 10 and will actuate, by a capillarity effect, the anti-FSH/colloidal gold assembly and FSH antigen.

As the migrating assembly will arrive at the region 2 having the anti-FSH polyclonal antibody, a second antigen-antibody reaction will occur which will be specific for the availability of three antihygienic places.

The "anchored" antibody will stop the assembly and the deposition will be made visible by a pink band, indicative of a positive result.

The migrating material, i.e. the complexed excess urine, will continue to displace by capillarity toward the right end portion of the strip 1, so as to safely react also with the anti-antibody material provided on the third region.

The latter reaction will always occur since it is independent from the presence of the FSH hormone in the urine.

Because of this characteristic and simple reaction between antibody and anti-antibody, which will be naturally mediated or driven, this further second "anchoring" will provide a second pink band which, in actual practice, will constitute a test control element.

In the case in which no FSH hormone is present in the urine, the urine which will have wet by capillarity the first region, will cause a driving or displacement of the antibody anti-FSH/colloidal gold assembly not bound to any antigens.

As the migrating assembly will arrive at the second region, it will be not captured, thereby no reaction will occur, and the second region will not have any coloured strip, thereby indicating a negative result.

The remaining sequence of the reaction occurs as previously disclosed, by forming a pink band at the third region.

The test must be repeated after about 15 days, since a positive result of the test merely indicates that, for the time, is present a concentration of the FSH hormone different from the normal concentration.

Since, however, the menstrual cycle has a duration of several days, which generally corresponds to the ov-

lation period, in which the FSH hormone increases to values of about 25 ml.U./ml, it is necessary to verify that the FSH hormone is constantly present at greater concentrations, thereby only a persistence of high levels will indicate an exhaustion of the ovulation function and a menopause condition.

From experimental tests, it has been found that a double positive result, obtained from tests performed at a distance of about 15 days from one another, provides an absolute warranty of the presence of the FSH hormone, thereby the user will be sure of her menopause physiologic condition.

Moreover, in the case in which one of the two tests provides a negative result, this is indicative of the fact that the woman is not in a menopause condition.

From the above disclosure it should be apparent that the invention fully achieves the intended aim and objects.

In particular, it is stressed the great simplicity of making of the test according to the present invention, which can be performed at home, without any discomfort and at a very reduced cost.

The invention, as disclosed, is susceptible to several variations and modifications, all of which will come within the scope of the invention. Moreover, all of the details can be replaced by other technically equivalent elements.

In practicing the invention, the used materials, provided that they are compatible to the intended use, as well as the contingent size and shapes, can be any, depending on to requirements.

Claims

1. A diagnostic test assembly for accurately and quickly detecting a clinical marker for diagnosing woman menopause, characterized in that said assembly comprises, on a supporting strip, a first region where is located and anti-FSH monoclonal antibody, a second region, adjoining the first region, where is located a polyclonal anti-FSH antibody, and a third region, adjoining the second region, where is located an anti-immunoglobuline IGG antibody which can bind with said monoclonal anti-FSH antibody.

2. A diagnostic test assembly, according to Claim 1, characterized in that said anti-FSH polyclonal antibody is deposited on and adhered in a dry form to the supporting strip.

3. A diagnostic test assembly, according to Claims 1 and 2, characterized in that said anti-FSH monoclonal antibody is provided on an absorbing paper layer, which has been dry impregnated and underlays an imbibition layer.

4. A diagnostic test assembly, according to one or more of the preceding claims, characterized in that said imbibition layer comprises absorbing paper bound to said supporting strip.

5. A diagnostic test assembly, according to one or more of the preceding claims, characterized in that said assembly further comprises, on said supporting strip, at the end thereof opposite to said impregnating layer, an absorbing layer, comprising and absorbing paper exclusively operating for absorbing the reaction liquid excess.

6. A diagnostic test assembly, according to one or more of the preceding claims, characterized in that said strip is packaged in an envelope having a circular window at said imbibition layer and a rectangular window at said second and third regions.

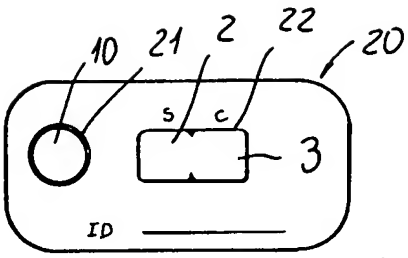

FIG. 2

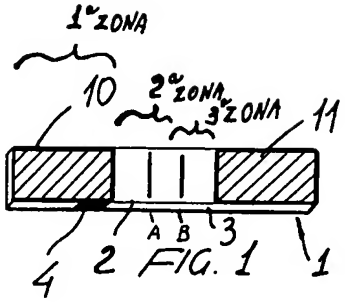

FIG. 1

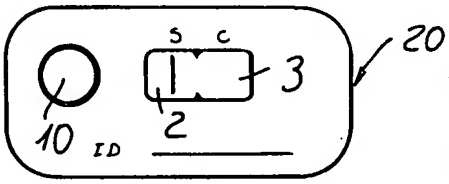

FIG. 3

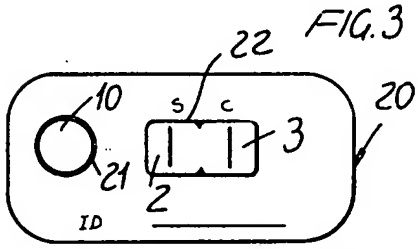

FIG. 4

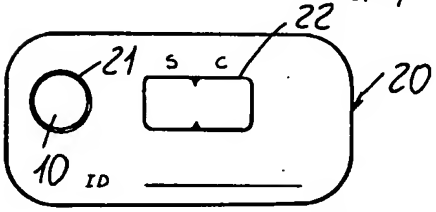

FIG. 5

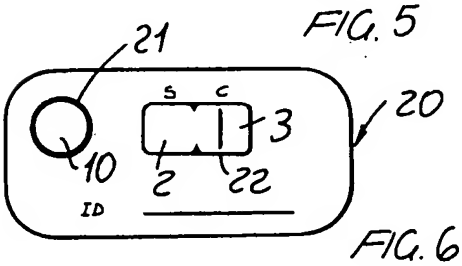

FIG. 6

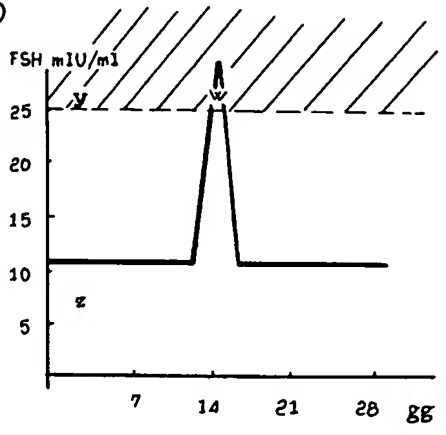

FIG. 7

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 83 0238

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP-A-0 349 215 (CARTER WALLACE) 3 January 1990 * abstract; claims 1-6; figure 1 *	1	G01N33/76 G01N33/558 G01N33/543 A61B5/00
A	ANNALS OF CLINICAL BIOCHEMISTRY, vol. 17, no. 1, January 1980, LONDON, pages 38-44, XP000195716 LOVESEY: "A rapid solid-phase radioimmunoassay for human plasma follicle-stimulating hormone" * abstract; figure 5 *	1	
A	EP-A-0 238 353 (SERONO DIAGNOSTICS PARTNERS A) 23 September 1987 * example 1 *	1	
A	WO-A-92 03738 (ENFER TECHNOLOGY LIMITED ;NEWBY MARTIN JOHN (GB)) 5 March 1992 * example 1 *	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

G01N
A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	5 July 1996	Ceder, O

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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